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15 Attorneys for Plaintiffs Bayer Schering Pharma AG
and Bayer HealthCare Pharmaceuticals Inc.

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18 **UNITED STATES DISTRICT COURT**
19 **DISTRICT OF NEVADA**

20

21 Bayer Schering Pharma AG and
Bayer Healthcare Pharmaceuticals Inc.,

22 Plaintiffs/Counterdefendants,

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vs.

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Lupin Limited

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Defendant/Counterclaimant

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and Lupin Pharmaceuticals, Inc.

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Defendant

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Case No. 2:10-cv-01166-GMN-RJJ

Bayer's Answer to Lupin's Counterclaims

1 Plaintiffs Bayer Schering Pharma AG and Bayer Healthcare Pharmaceuticals Inc.
2 (collectively “Bayer”) respond as follows to the Counterclaims filed by Defendant Lupin Limited
3 (“Lupin Ltd.”). (Doc. 10.) Answers to Lupin Ltd.’s specific allegations are contained below in
4 numbered paragraphs that correspond to the numbered paragraphs of Lupin Ltd.’s Counterclaims.
5 Bayer denies any allegations not expressly admitted in this Answer.

COUNTERCLAIMS

The unnumbered paragraph entitled “Counterclaims” contains prefatory language to which no response is required. To the extent that this paragraph is deemed to contain factual allegations, Bayer denies them.

THE PARTIES

11	1.	Admitted.
12	2.	Admitted.
13	3.	Admitted.

BACKGROUND

15 4. On information and belief, Bayer admits that Defendants Lupin Ltd. and Lupin
16 Pharmaceuticals, Inc. (collectively, “Lupin”) filed ANDA No. 20-1661 seeking approval to market
17 a generic version of Bayer’s YAZ® oral contraceptive (“Lupin’s YAZ® ANDA product”). Bayer
18 further admits that its YAZ® oral contraceptive is the subject of New Drug Application Nos. 21-
19 676, 21-873, and 22-045. Bayer is without knowledge to admit or deny any of the remaining
20 allegations in Paragraph 4.

21 5. Bayer admits that the patents listed in Paragraph 5 appear in the FDA's Orange
22 Book for NDA No. 21-676. The remainder of Paragraph 5 contains legal conclusions to which no
23 response is required. To the extent that the remainder of Paragraph 5 is deemed to contain factual
24 allegations, Bayer denies them.

25 6. Paragraph 6 contains legal conclusions to which no response is required. To the
26 extent that Paragraph 6 is deemed to contain factual allegations, Bayer denies them.

1 7. Bayer is without information sufficient to admit or deny the allegations in
2 Paragraph 7.

3 8. Bayer admits that Lupin sent Bayer a letter on June 2, 2010 providing notice that it
4 had filed paragraph IV certifications for the patents identified in Paragraph 8. The remainder of
5 Paragraph 8 contains legal conclusions to which no response is required. To the extent that the
6 remainder of Paragraph 8 is deemed to contain factual allegations, Bayer denies them.

JURISDICTION AND VENUE

8 ||| 9. Bayer incorporates its above responses in response to Paragraph 9.

9 10. Paragraph 10 contains legal conclusions to which no response is required. To the
10 extent that Paragraph 10 is deemed to contain factual allegations, Bayer denies them.

11 11. Paragraph 11 contains legal conclusions to which no response is required. To the
12 extent that Paragraph 11 is deemed to contain factual allegations, Bayer denies them.

13 12. Paragraph 12 contains legal conclusions to which no response is required. To the
14 extent that Paragraph 12 is deemed to contain factual allegations, Bayer denies them.

15 13. Admitted.

LUPIN LIMITED IS ENTITLED TO DECLARATORY JUDGMENT

17 14. Bayer admits that it filed a complaint against Lupin on July 15, 2010, alleging
18 infringement of U.S. Reissue Patent Nos. 27,564, 27,838, and 28,253 under 35 U.S.C. § 271(e).
19 Otherwise denied.

20 15. Bayer admits that it filed a complaint against Lupin on July 15, 2010, alleging
21 infringement of U.S. Reissue Patent Nos. 27,564, 27,838, and 28,253 under 35 U.S.C. § 271(e).
22 The remainder of Paragraph 15 contains legal conclusions to which no response is required. To
23 the extent that the remainder of Paragraph 15 is deemed to contain factual allegations, Bayer
24 denies them.

25 16. Paragraph 16 contains legal conclusions to which no response is required. To the
26 extent that Paragraph 16 is deemed to contain factual allegations, Bayer denies them.

1 17. Paragraph 17 contains legal conclusions to which no response is required. To the
2 extent that Paragraph 17 is deemed to contain factual allegations, Bayer denies them.

3 18. Paragraph 18 contains legal conclusions to which no response is required. To the
4 extent that Paragraph 18 is deemed to contain factual allegations, Bayer denies them.

5 | 19. Admitted.

6 | 20. Admitted.

7 21. Bayer admits that the Court entered a Consent Judgment Of Non-Infringement For
8 Certain Of Plaintiffs' Patents on March 18, 2009 in the case *Bayer Schering Pharma AG, et al. v.*
9 *Sandoz, Inc., et al.*, Case No. 2:08-cv-00995-KJD-GWF consolidated with 2:07-cv-01472-KJD-
10 GWF (D. Nev.) (Doc. 54). Bayer admits the allegations in Paragraph 21 to the extent they are
11 consistent with this consent judgment. To the extent that Paragraph 21 contains factual allegations
12 that are inconsistent with this consent judgment, Bayer denies them.

13 22. Bayer admits that the Court entered a Consent Judgment Of Non-Infringement For
14 Certain Of Plaintiffs' Patents on September 22, 2009 in the case *Bayer Schering Pharma AG, et*
15 *al. v. Sandoz, Inc., et al.*, Case No. 2:08-cv-00995-KJD-GWF consolidated with 2:07-cv-01472-
16 KJD-GWF (D. Nev.) (Doc. 122). Bayer admits the allegations in Paragraph 22 to the extent they
17 are consistent with this consent judgment. To the extent that Paragraph 22 contains factual
18 allegations that are inconsistent with this consent judgment, Bayer denies them.

FIRST CLAIM FOR RELIEF

Declaration of Invalidity of the '564 Reissue Patent

21 23. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
22 23.

23 | 24. Denied.

24 25. Paragraph 25 contains legal conclusions to which no response is required. To the
25 extent that Paragraph 25 is deemed to contain factual allegations, Bayer denies them.

SECOND CLAIM FOR RELIEF

Declaration of Noninfringement of the ‘564 Reissue Patent

26. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

4 | 26

5 | 27. Denied.

6 28. Paragraph 28 contains legal conclusions to which no response is required. To the
7 extent that Paragraph 28 is deemed to contain factual allegations, Bayer denies them.

THIRD CLAIM FOR RELIEF

Declaration of Invalidity of the '838 Reissue Patent

10 ||| 29. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

11 | 29

12 30. Denied.

13 31. Paragraph 31 contains legal conclusions to which no response is required. To the
14 extent that Paragraph 31 is deemed to contain factual allegations, Bayer denies them.

FOURTH CLAIM FOR RELIEF

Declaration of Noninfringement of the ‘838 Reissue Patent

32. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

18 | 32

19 33. Denied.

34. Paragraph 34 contains legal conclusions to which no response is required. To the
extent that Paragraph 34 is deemed to contain factual allegations, Bayer denies them.

FIFTH CLAIM FOR RELIEF

Declaration of Invalidity of the '253 Reissue Patent

35. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

25 | 35

26 | 36. Denied.

1 37. Paragraph 37 contains legal conclusions to which no response is required. To the
2 extent that Paragraph 37 is deemed to contain factual allegations, Bayer denies them.

SIXTH CLAIM FOR RELIEF

Declaration of Noninfringement of the ‘253 Reissue Patent

5 38. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
6 38.

7 || 39. Denied.

8 40. Paragraph 40 contains legal conclusions to which no response is required. To the
9 extent that Paragraph 40 is deemed to contain factual allegations, Bayer denies them.

SEVENTH CLAIM FOR RELIEF

Declaration of Invalidity of the ‘652 Patent

12 41. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
13 41.

14 42. Denied.

15 43. Paragraph 43 contains legal conclusions to which no response is required. To the
16 extent that Paragraph 43 is deemed to contain factual allegations, Bayer denies them.

EIGHTH CLAIM FOR RELIEF

Declaration of Noninfringement of the ‘652 Patent

19 44. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
20 44.

21 45. Denied.

22 46. Paragraph 46 contains legal conclusions to which no response is required. To the
23 extent that Paragraph 46 is deemed to contain factual allegations, Bayer denies them.

NINTH CLAIM FOR RELIEF

Declaration of Invalidity of the ‘338 Patent

26 47. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
27 47.

48. Denied.

49. Paragraph 49 contains legal conclusions to which no response is required. To the extent that Paragraph 49 is deemed to contain factual allegations, Bayer denies them.

TENTH CLAIM FOR RELIEF

Declaration of Noninfringement of the ‘338 Patent

50. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

50.

51. Denied.

9 52. Paragraph 52 contains legal conclusions to which no response is required. To the
10 extent that Paragraph 52 is deemed to contain factual allegations, Bayer denies them.

ELEVENTH CLAIM FOR RELIEF

Declaration of Invalidity of the ‘395 Patent

53. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

14 | 53.

54. Denied.

16 55. Paragraph 55 contains legal conclusions to which no response is required. To the
17 extent that Paragraph 55 is deemed to contain factual allegations, Bayer denies them.

TWELFTH CLAIM FOR RELIEF

Declaration of Noninfringement of the ‘395 Patent

56. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

21 | 56.

57. Denied.

23 58. Paragraph 58 contains legal conclusions to which no response is required. To the
24 extent that Paragraph 58 is deemed to contain factual allegations, Bayer denies them.

THIRTEENTH CLAIM FOR RELIEF

Declaration of Invalidity of the ‘326 Patent

3 59. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
4 59.

5 60. Denied.

6 Paragraph 61 contains legal conclusions to which no response is required. To the
7 extent that Paragraph 61 is deemed to contain factual allegations, Bayer denies them.

FOURTEENTH CLAIM FOR RELIEF

Declaration of Noninfringement of the ‘326 Patent

10 62. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
11 62

12 || 63. Denjed.

13 64. Paragraph 64 contains legal conclusions to which no response is required. To the
14 extent that Paragraph 64 is deemed to contain factual allegations, Bayer denies them.

FIFTEENTH CLAIM FOR RELIEF

Declaration of Invalidity of the ‘931 Patent

17 65. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
18 65

19 66 Denied

20 67. Paragraph 67 contains legal conclusions to which no response is required. To the
21 extent that Paragraph 67 is deemed to contain factual allegations, Bayer denies them.

SIXTEENTH CLAIM FOR RELIEF

Declaration of Noninfringement of the '931 Patent

24 68. Bayer incorporates its above responses to Paragraphs 1-22 in response to
25 Paragraph 68.

36 | 69 Denied

1 70. Paragraph 70 contains legal conclusions to which no response is required. To the
2 extent that Paragraph 70 is deemed to contain factual allegations, Bayer denies them.

PRAYER FOR RELIEF

The numbered Paragraphs following the heading “Prayer for Relief” are requests for relief to which no response is required. To the extent any of these numbered Paragraphs are deemed to contain factual allegations, Bayer denies them and denies that Lupin is entitled to any of the relief requested therein or to any relief whatsoever.

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CERTIFICATE OF SERVICE

Pursuant to Fed. R. Civ. P. 5(b), I certify that on October 21, 2010, I caused a true and correct copy of the foregoing to be transmitted electronically through the Court's e-filing electronic notice system following counsel of record:

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